FEB 2 6 2014

Sec 005_510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: **2014-01-05**
Submission Numbers for Pre-Submission: **K123162**

1. Submitter Name and Address:

Name:	U&U Medical Technology Co., Ltd
Address:	Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
Contactor Name:	Garfield Wang
TEL:	+86-13902471751
E-mail:	Wangxuebo_11@hotmail.com
US Agent:	Pan Angels Corp.
Address:	3330 Fowler Street,Los Angeles, CA 90063,U.S.A
TEL:	(323)422-8581
Contact person :	Mr. Michael Kim

2. Submission Devices Information:

Trade/Proprietary Name: U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll
Common Name: Plasma Sterilization Pouch / Roll
Classification name: Sterilization Wrap
Class: II
FDA review panel code: INCB
Product code: FRG - sterilization wrap
CFR Regulation Number: 21CFR 880.6850

3. Predicate Devices Information:

Trade Name:	Tyvek Pouch/Roll with STERRAD Chemical Indicator
510(K) Number:	K103210
Manufacturer:	Advanced Sterilization Products Company.

4. Devices Description:

The U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll are manufactured from TYVEK and medical plastic film that are heat sealed on three sides. The fourth side has an adhesive tape that is used to seal the pouch or heat-sealed by the heat-seal machine. The TYVEK conforms to recognized material standards and can be sterilized by STERRAD 100 NX Hydrogen Peroxide Gas Plasma. The Sterilization Pouch has the same intended use, Essential Component, Raw material, Sterilization method, manufacturing methods and same technological characteristics as these predicate devices. Substantial equivalent to the predicate device was established by physical testing of the TYVEK (pressure drop vs. flow and filtration efficiency) and film (thickness, tensile strength and elongation) from non-sterile, sterilized finished devices, as well as, performance of these finished devices (seal strength, package burst, dye migration).

The pouches are manufactured from TYVEK that is thermally sealed to laminated film on the left, right, and bottom of pouch. The fourth side has an adhesive tape that is used to that is

used to seal the pouch or heat-sealed by the heat-seal machine prior to sterilization of the enclosed medical device.

5. Model numbers of the pouches:

Ref Number	Model Number	Description	Size
UUP0001	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	3" X 8"
UUP0002	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	4" X 10.25"
UUP0003	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	6" X 12.5"
UUP0004	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	4" X 14"
UUP0005	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	8" X 16"
UUP0006	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	6" X 16.5"
UUP0007	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	10" X 19"
UUP0008	UUP	TYVEK Pouch-Heat-Seal and Self-Seal	12.5" X 22"
UUR0001	UUR	TYVEK Roll-Heat-seal	3" X 228'
UUR0002	UUR	TYVEK Roll-Heat-seal	4" X 228'
UUR0003	UUR	TYVEK Roll-Heat-seal	6" X 228'
UUR0004	UUR	TYVEK Roll-Heat-seal	14" X 228'
UUR0005	UUR	TYVEK Roll-Heat-seal	16.5" X 228'
UUR0006	UUR	TYVEK Roll-Heat-seal	20" X 228'

5. Intended Use:

U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD 100NX Hydrogen Peroxide Gas Plasma sterilizer.

The recommended Hydrogen Peroxide Gas Plasma cycle parameter:
STERRAD 100NX STANDARD Cycle

Sterilization load claim:

STERRAD 100NX Sterilizer Standard cycle:

- General medical instruments (metal and nonmetal, including hinged devices)
- Instruments with single-channel stainless steel lumens with an Internal diameter 3 mm or larger and length 150 mm or shorter.
- Polyethylene and Teflon lumen tubing with an internal diameter of 3 mm or larger and length of 500 mm or shorter.
- These items must be sterilized without any additional load items
- Limit of 20 pieces of tubing per cycle

Load condition: One device per Sterilization Pouch.
Load chamber: Two shelves (total weight: 21.4 lbs or 9.7 kg)
Load Pouch: Leave enough material beyond the seal for the opener to easily grasp (usually 1- 1 ¼ inches).

SHELF LIFE: It is recommended that the products are put to their end use within 2 years of manufacture. The recommended "best before" date and the manufacturing date are stated on the label. **This device was demonstrated to maintain sterility of the contents for 30 days after Sterilization.**

6. Technological Characteristics:

Performance testing was conducted to show that the U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll maintain sterility until the seal of the Pouch/Roll is opened.

6.1 Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll Performance Tests

Element	Results
Sterilant Penetration	*PASSED*
Package Integrity	*PASSED*
Maintenance of Package Integrity	*PASSED*
Material Compatibility	*PASSED*
Shelf-Life	*PASSED*
Biocompatibility	*PASSED*
Performances	*PASSED*
Biocompatibility	*PASSED*

6.2 Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll Comparison Table

Element of Comparison	Submission Device	Predicate Device K103210
Pouch Construction: Tyvek	YES	YES
Film	YES	YES
User Heat Seal	YES	YES
User Self Seal	YES	YES
Single Use Device	YES	YES
Shelf- Life	2 Years, This device was demonstrated to maintain sterility of the contents for 30 days after Sterilization.	2 Years
Labeling	Meet the requirements of 21 CFR Part 801	Meet the requirements of 21 CFR Part 801

7. Conclusion:

The materials, intended use, performance, function, and operational features of both the submitted device and the predicate device are substantially equivalent.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

U&U Medical Technology Company, Limited
Mr. Garfield Wang
General Manager
Dongshou Village, Hengshanqiao, Changzhou, Jiengsu
213119 CHINA

Re: K123162
Trade/Device Name: U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 23, 2014
Received: January 29, 2014

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

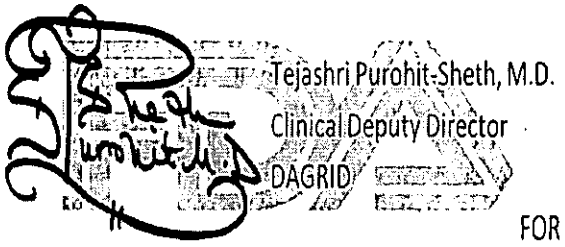
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sec 004_Indications for Use

510(k) Number (if known): K123162

Device Name: U&U Hydrogen Peroxide Gas Plasma Sterilization Pouch / Roll

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Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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